

REMARKS

Applicants further submit new, current evidence that the problems of underutilization and compliance in the treatment of cardiovascular disease still exist in the medical field. Exhibit 7, submitted herewith, is a recent article by Elizabeth A. McGlynn et al. entitled "The Quality of Health Care Delivered to Adults in the United States," New England Journal of Medicine, Vol. 348, June 26, 2003, pages 2635-2645. This recent study documents poor adherence to many recommended care practices. For example, participants did not get 32 percent of the appropriate care for coronary artery disease (such as beta-blockers or aspirin after myocardial infarction). The study concludes that it identifies serious threats to the health of the American public in adherence to recommended processes for basic care and that strategies to reduce these deficits in care are warranted.


Exhibit 8, submitted herewith, is an editorial by Earl P. Steinberg, M.D., M.P.P., entitled "Improving the Quality of Care – Can We Practice What We Preach?," New England Journal of Medicine, Vol. 348, June 26, 2003, pages 2681-2683. In this editorial, the author questions what it will take to do better. The author lists four actions. First, quality of care should be measured and reported routinely at both the national and provider-specific levels. Second, greater use of information technology must be made. Third, in addition to capitalizing on the power of computers, the profession should draw on the power of patients to improve the quality of care they receive and their health outcomes. Fourth, current financial incentives that often discourage quality improvement must be addressed. Interestingly, Steinberg offers a number of solutions to improve health care delivery; making treatments more

convenient is not one of them.

Exhibit 9, submitted herewith, is an article by Anthony Rodgers entitled "A cure for cardiovascular disease?," British Medical Journal, Vol. 326, June 28, 2003, pages 1407-1408. This article refers to a paper in the same issue of the BMJ about a combination treatment pill for cardiovascular disease. The pill is called the Polypill and it has several components including beta-blockers, lipid lowering agents, aspirin, etc.

The three new Exhibits provide further evidence that the solutions to problems with compliance and under-utilization of helpful medications for cardiovascular treatments are elusive, and have troubled the healthcare industry for a long time, even to this day. The industry continues to struggle to find answers to these perplexing questions.

Respectfully submitted,



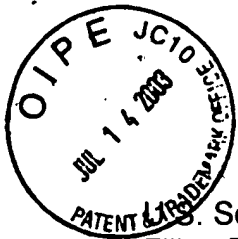
Dated: 7-11-03

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: MS – Non Fee Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on July 11, 2003:

Robert R. Deleault
Attorney for Applicants



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.: 09/717,746
Filing Date: 11/21/2000
Applicants: Herbert M. Dean et al.
Title: CARDIOPROTECTIVE DOSAGE UNITS
Art Unit: 1614
Examiner: Donna A. Jagoe

1614
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MS – Non Fee Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filling in the above-referenced patent application please find a Supplemental Response with Exhibits and a return postcard.

Respectfully submitted,

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Dated: 7-11-03

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Robert R. Deleault

This Week in the Journal

June 26, 2003

The Quality of Health Care Delivered to Adults in the United States

This national study of the quality of health care documents poor adherence to many recommended care practices. For example, participants did not receive 34 percent of the recommended immunizations, did not get 32 percent of the appropriate care for coronary artery disease (such as beta-blockers or aspirin after myocardial infarction), and did not get 55 percent of the recommended care for diabetes.

Deficiencies in the quality of care are common in the United States. Monitoring of national data on quality may guide efforts to improve health care delivery.

[Related Editorial](#)

SPECIAL ARTICLE

The Quality of Health Care Delivered to Adults in the United States

Elizabeth A. McGlynn, Ph.D., Steven M. Asch, M.D., M.P.H., John Adams, Ph.D., Joan Keesey, B.A., Jennifer Hicks, M.P.H., Ph.D., Alison DeCristofaro, M.P.H., and Eve A. Kerr, M.D., M.P.H.

ABSTRACT

BACKGROUND

We have little systematic information about the extent to which standard processes involved in health care — a key element of quality — are delivered in the United States.

METHODS

We telephoned a random sample of adults living in 12 metropolitan areas in the United States and asked them about selected health care experiences. We also received written consent to copy their medical records for the most recent two-year period and used this information to evaluate performance on 439 indicators of quality of care for 30 acute and chronic conditions as well as preventive care. We then constructed aggregate scores.

RESULTS

Participants received 54.9 percent (95 percent confidence interval, 54.3 to 55.5) of recommended care. We found little difference among the proportion of recommended preventive care provided (54.9 percent), the proportion of recommended acute care provided (53.5 percent), and the proportion of recommended care provided for chronic conditions (56.1 percent). Among different medical functions, adherence to the processes involved in care ranged from 52.2 percent for screening to 58.5 percent for follow-up care. Quality varied substantially according to the particular medical condition, ranging from 78.7 percent of recommended care (95 percent confidence interval, 73.3 to 84.2) for senile cataract to 10.5 percent of recommended care (95 percent confidence interval, 6.8 to 14.6) for alcohol dependence.

CONCLUSIONS

The deficits we have identified in adherence to recommended processes for basic care pose serious threats to the health of the American public. Strategies to reduce these deficits in care are warranted.

From RAND, Santa Monica, Calif. (E.A.M., S.M.A., J.A., J.K., J.H., A.D.); the Veterans Affairs (VA) Greater Los Angeles Health Care System, Los Angeles (S.M.A.); the Department of Medicine, University of California Los Angeles, Los Angeles (S.M.A.); the VA Center for Practice Management and Outcomes Research, VA Ann Arbor Health Care System, Ann Arbor, Mich. (E.A.K.); and the Department of Medicine, University of Michigan, Ann Arbor (E.A.K.). Address reprint requests to Dr. McGlynn at RAND, 1700 Main St., P.O. Box 2138, Santa Monica, CA 90407, or at beth_mcglynn@rand.org.

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THE DEGREE TO WHICH HEALTH CARE in the United States is consistent with basic quality standards is largely unknown.^{1,2} Although previous studies have documented serious quality deficits, they provide a limited perspective on the issue.³⁻⁵ Most have assessed a single condition,^{6,7} a small number of indicators of quality,^{8,9} persons with a single type of insurance coverage,¹⁰ or persons receiving care in a small geographic area.^{11,12} The few national studies have been limited to specific segments of the population, such as Medicare beneficiaries¹³⁻¹⁵ or enrollees in managed-care plans¹⁶; have focused on a limited set of topics, such as preventive care,¹⁷ diabetes,¹⁸ or human immunodeficiency virus¹⁹; or have assessed health outcomes without a link to specific processes involved in care.²⁰ As a result, we have no comprehensive view of the level of quality of care given to the average person in the United States. This information gap contributes to a persistent belief that quality is not a serious national problem.¹

In this article, we report results from the Community Quality Index (CQI) study, a collateral study of the Community Tracking Study (CTS).²¹ The CTS, conducted by the Center for Studying Health System Change (CSHSC), monitors changes in health care markets in the United States. The CTS obtains self-reported information from a random sample of the U.S. population on their insurance coverage, patterns of utilization of health care services, and health status. The CSHSC has reported on trends in health care costs,²² factors affecting the choice of employer-sponsored or public insurance,²³ and changes in the structure of managed-care plans.²⁴ However, the CTS lacks detailed information about the implications of these variations in health care markets for the quality of health care. By collaborating with the CSHSC, we were able to assess the extent to which the recommended processes of medical care — one critical dimension of quality — are delivered to a representative sample of the U.S. population for a broad spectrum of conditions.

METHODS

RECRUITMENT OF PARTICIPANTS

In 12 metropolitan areas (Boston; Cleveland; Greenville, S.C.; Indianapolis; Lansing, Mich.; Little Rock, Ark.; Miami; Newark, N.J.; Orange County, Calif.; Phoenix, Ariz.; Seattle; and Syracuse, N.Y.), using random-digit-dial telephone surveys, the CTS deliberately recruited enough participants to assess how

structural characteristics in each market (e.g., the penetration of managed care) affect patterns of access to and utilization of health care services. Between October 1998 and August 2000, we recontacted by telephone households that had participated in the CTS interviews. Participants were asked to complete a telephone interview regarding their health history and to provide a listing of all individual or institutional health care providers whom they had seen during the previous two years. Participants who orally agreed to provide access to their medical records were sent written consent forms to sign and return to RAND. Photocopies of the medical records of participants providing written consent were sent to RAND for central abstracting.

RESPONSE RATES

Because of the complex, multistage nature of the study design, several calculations of the response rate are provided. Among the 20,028 adults in the initial sample, 2091 (10 percent) were deemed ineligible, primarily because they had left the area. Among the 17,937 eligible adults, 13,275 (74 percent) participated in the telephone interview regarding their health history, including 863 (7 percent) who had had no visits to a health care provider during the previous two years. Among the 12,412 participants who had had visits, 10,404 (84 percent) agreed orally to provide access to their medical records. We obtained written consent from 7528 (61 percent of those with visits to a provider). Participants reported having seen between 1 and 17 providers (mean, 2.6) during the study period. We obtained at least one record for 6712 (89 percent) of those who returned their consent forms. Overall, we received 84 percent of the records for which we had consent forms; we received all expected records for 4612 of the 6712 participants with consent forms and records (69 percent) and all but one record for 1547 of these participants (23 percent). Sensitivity analyses revealed few differences in results related to the completeness of records, so all participants for whom we obtained at least one record were included in the results we report (37 percent of the sample of eligible adults).

DEVELOPMENT OF INDICATORS OF QUALITY

The indicators of quality used in the study were derived from RAND's Quality Assessment Tools system.²⁵ RAND staff members selected acute and chronic conditions that represented the leading causes of illness, death, and utilization of health

care in each age group, as well as preventive care related to these causes. For each condition, staff physicians reviewed established national guidelines and the medical literature and proposed indicators of quality for all phases of care or medical functions (screening, diagnosis, treatment, and follow-up). We developed indicators to assess potential problems with the overuse and underuse of key processes. We primarily chose measures of processes as indicators, because they represent the activities that clinicians control most directly, because they do not generally require risk adjustment beyond the specification of eligibility, and because they are consistent with the structure of national guidelines.^{5,26}

Four nine-member, multispecialty expert panels were convened to assess the validity of the indicators proposed by the staff, using the RAND–UCLA modified Delphi method.²⁷ The members of the panels, nominated by the appropriate specialty societies, were diverse with respect to geography, practice setting, and sex. Indicators were rated on a 9-point scale (with 1 denoting not valid and 9 very valid). Only indicators with a median validity score of 7 or higher were included in the Quality Assessment Tools system. This method of selecting indicators is reliable²⁸ and has been shown to have content, construct, and predictive validity in other applications.^{29–32}

The criteria for the selection of conditions, reviews of the literature, the process followed by the panels, and the final indicators have been published elsewhere.^{33–36} (Further information on all the quality indicators used in this study is available at http://www.rand.org/health/mcglynn_appa.pdf or from the National Auxiliary Publications Service.*) Table 1 provides a brief description and classifications for a sample of the indicators we used. The classifications enabled us to examine quality from the perspective of what is being done (type of care), why it is being done (function), how it is being delivered (mode), and the nature of the quality problem (underuse or overuse). Results are based on 439 indicators for 30 conditions and preventive care.

HEALTH HISTORY INTERVIEW

We obtained selective information directly from respondents to augment information in their medical records. The health history took an average of 13 minutes to complete. The data obtained in this in-

terview were used to refine the analysis of a respondent's eligibility for inclusion in the analysis or to augment the scoring for 22 of the 439 indicators. For example, we used reports of symptoms from participants with asthma to classify those with moderate-to-severe disease. We augmented scores for influenza or pneumococcal immunizations and screening for cancer on the basis of self-reports.

ABSTRACTING OF CHARTS

We developed computer-assisted abstraction software on a Visual Basic platform (version 6.0, Microsoft). The software allowed the manual abstraction of charts to be tailored to the specific record being reviewed and provided interactive checks of the quality of the data (for consistency and range), calculations (e.g., the determination of the presence of high blood pressure), and classifications (e.g., the determination of drug class) during abstraction.

Data for the study were abstracted by 20 trained registered nurses who had successfully abstracted a complex standard chart after a two-week training program. Charts were abstracted separately for each health care provider of each participant (i.e., at the dyad level). The average time required to abstract a chart for a participant–provider dyad was 50 minutes.

To assess interrater reliability, we re-abstracted charts from a randomly selected 4 percent sample of participants. Average reliability, with the use of the kappa statistic, ranged from substantial to almost perfect³⁷ at three levels: the presence or absence of a given condition ($\kappa=0.83$), the participant's eligibility for the process represented by a given indicator ($\kappa=0.76$), and scoring of a given indicator ($\kappa=0.80$).

STATISTICAL ANALYSIS

We specified the combination of variables necessary to determine whether each participant was or was not eligible for the process specified by each indicator and whether each participant did or did not receive each process or some proportion of it. Each indicator was scored at one of three levels — that of the individual participant, that of the participant–provider dyad, or that of the episode — depending on the nature of the process being evaluated. The level at which an indicator was scored affected the number of times a participant was eligible for the specified process; the resulting number served as the denominator in the calculation of the aggregate score. For participant-level indicators, we gave

*See NAPS document no. 05610 for 50 pages of supplementary material. To order, contact NAPS, c/o Microfiche Publications, 248 Hempstead Tpke., West Hempstead, NY 11552.

Table 1. Selected Quality-of-Care Indicators and Classifications Used in the Community Quality Index Study.*

Condition†	Description of Selected Indicator	Classification for Aggregate Scores			
		Type of Care	Function	Mode	Problem with Quality
Alcohol dependence (5 indicators)					
Indicator 2	Assessment of alcohol dependence among regular or binge drinkers	For chronic condition	Diagnosis	History	Underuse
Indicator 4	Treatment referral for persons given a diagnosis of alcohol dependence	For chronic condition	Treatment	Encounter or other intervention	Underuse
Asthma (25 indicators)					
Indicator 4	Long-acting agents for patients with frequent use of short-acting beta-agonists	For chronic condition	Treatment	Medication	Underuse
Indicator 6	Inhaled corticosteroids for patients receiving long-term systemic corticosteroid therapy	For chronic condition	Treatment	Medication	Underuse
Breast cancer (9 indicators)					
Indicator 1	Appropriate follow-up of palpable mass	For chronic condition	Diagnosis	Laboratory testing or radiography	Underuse
Indicator 5	Choice of surgical treatments for stage I or II cancer	For chronic condition	Treatment	Surgery	Underuse
Cerebrovascular disease (10 indicators)					
Indicator 4	Antiplatelet therapy for noncardiac stroke or transient ischemic attack	For chronic condition	Treatment	Medication	Underuse
Indicator 5	Carotid imaging for patients with symptomatic cardiovascular disease or transient ischemic attack	For chronic condition	Diagnosis	Laboratory testing or radiography	Underuse
Colorectal cancer (12 indicators)					
Indicator 1	Screening for high-risk patients starting at 40 yr of age	Preventive	Screening	Laboratory testing or radiography	Underuse
Indicator 7	Appropriate surgical treatment	For chronic condition	Treatment	Surgery	Underuse
Congestive heart failure (36 indicators)					
Indicator 1	Ejection fraction assessed before medical therapy	For chronic condition	Diagnosis	Laboratory testing or radiography	Underuse
Indicator 32	ACE inhibitors for patients with congestive heart failure and an ejection fraction <40%	For chronic condition	Treatment	Medication	Underuse
Coronary artery disease (37 indicators)					
Indicator 3	Counseling on smoking cessation	For chronic condition	Treatment	Counseling or education	Underuse
Indicator 11	Avoidance of nifedipine for patients with an acute myocardial infarction	For chronic condition	Treatment	Medication	Overuse
Diabetes (13 indicators)					
Indicator 9	Diet and exercise counseling	For chronic condition	Treatment	Counseling or education	Underuse
Indicator 12	ACE inhibitors for patients with proteinuria	For chronic condition	Treatment	Medication	Underuse

Table 1. (Continued.)

Condition	Description of Selected Indicator	Classification for Aggregate Scores			
		Type of Care	Function	Mode	Problem with Quality
Headache (21 indicators)					
Indicator 11	CT or MRI for patients with new-onset headache and an abnormal neurologic examination	Acute	Diagnosis	Laboratory testing or radiography	Underuse
Indicator 15	Use of appropriate first-line agents for patients with acute migraine	Acute	Treatment	Medication	Overuse
Hip fracture (9 indicators)					
Indicator 6	Prophylactic antibiotics given on day of hip-repair surgery	Acute	Treatment	Medication	Underuse
Indicator 7	Prophylactic antithrombotic drugs given on admission for patients with hip fracture	Acute	Treatment	Medication	Underuse
Hyperlipidemia (7 indicators)					
Indicator 4	Treatment of high LDL cholesterol levels in patients with coronary artery disease	For chronic condition	Treatment	Medication	Underuse
Hypertension (27 indicators)					
Indicator 16	Lifestyle modification for patients with mild hypertension	For chronic condition	Treatment	Counseling or education	Underuse
Indicator 18	Pharmacotherapy for uncontrolled mild hypertension	For chronic condition	Treatment	Medication	Underuse
Indicator 27	Change in treatment when blood pressure is persistently uncontrolled	For chronic condition	Follow-up	Medication	Underuse
Acute low back pain (6 indicators)					
Indicator 1	Rule out cancer, fracture, infection, cauda equina syndrome, and neurologic causes	Acute	Diagnosis	History	Underuse
Indicator 6	Avoidance of prolonged bed rest	Acute	Treatment	Other	Overuse
Preventive care (38 indicators)					
Indicator 1	Screening for problem drinking	Preventive	Screening	History	Underuse
Indicator 2	Mammographic screening for breast cancer	Preventive	Screening	Laboratory testing or radiography	Underuse
Indicator 3	Screening for colorectal cancer in persons at average risk	Preventive	Screening	Laboratory testing or radiography	Underuse
Indicator 8	Influenza vaccine for persons ≥ 65 yr of age	Preventive	Treatment	Immunization	Underuse
Indicator 21	HIV testing for those at risk	Preventive	Screening	Laboratory testing or radiography	Underuse
Indicator 25	Screening for cervical cancer	Preventive	Screening	Laboratory testing or radiography	Underuse
Indicator 29	Smoking status documented	Preventive	Screening	History	Underuse
Indicator 31	Annual advice for smokers to quit smoking	Preventive	Treatment	Counseling or education	Underuse

Table 1. (Continued.)

Condition	Description of Selected Indicator	Classification for Aggregate Scores			
		Type of Care	Function	Mode	Problem with Quality
Sexually transmitted diseases (26 indicators)					
Indicator 9	Chlamydia screening for high-risk women	Preventive	Screening	Laboratory testing or radiography	Underuse
Indicator 24	HIV screening in patients with sexually transmitted diseases	Acute	Screening	Laboratory testing or radiography	Underuse

* ACE denotes angiotensin-converting enzyme, CT computed tomography, MRI magnetic resonance imaging, LDL low-density lipoprotein, and HIV human immunodeficiency virus.

† The number of indicators given in parentheses after each condition is the total number of indicators of quality of care for that condition; the indicators listed below each condition are examples.

the participant a score of "pass" if at least one of his or her health care providers had delivered the indicated care (e.g., influenza vaccination). For indicators scored at the level of the participant-provider dyad (e.g., smoking status noted in the chart), we scored every dyad separately, so the number of times the participant was counted in the denominator depended on the number of providers who saw the participant and could have performed the specified process. For indicators scored at the episode level (e.g., follow-up after hospitalization for an exacerbation of asthma), we scored every event rendering the participant eligible for the specified process and involving any of the participant's providers, so the number of eligibility events depended on the number of episodes that occurred.

In order to produce aggregate scores, we divided all instances in which recommended care was delivered by the number of times participants were eligible for indicators in the category. For example, Table 1 presents information about seven of the indicators for acute care; the number of times participants were eligible for these indicators would constitute the denominator for the acute care score. The results are presented as proportions, theoretically ranging in value from 0 to 100 percent. We used the bootstrap method to estimate standard errors directly for all the aggregate scores.³⁸

Because everyone in the initial sample for the CQI study had participated in the CTS, we had a rich set of variables for assessing nonresponse. We used logistic-regression analysis to estimate the relations between individual characteristics (age, sex, race, educational level, income, self-reported level of use of physicians and hospitals, insurance status, and

health status) and participation in the study. In general, participants tended to be older than nonparticipants ($P<0.001$) and were more likely than nonparticipants to be female ($P<0.001$) and white ($P<0.001$), with higher levels of education ($P<0.001$) and income ($P<0.001$). They were also more likely to have used health care services ($P<0.001$) and to be in other than excellent health ($P=0.03$). We used the coefficients from the regression equation to adjust the scores for nonresponse, and we weighted the data for the participants to be representative of the population from which they were drawn.

RESULTS

CHARACTERISTICS OF THE PARTICIPANTS

Table 2 summarizes the characteristics of the participants; these characteristics differ from population averages but parallel the profile of persons receiving medical care. For example, the average age of patients in the National Ambulatory Medical Care Survey³⁹ is 44.7 years. Women have higher rates of visits than men (319.9 vs. 234.9 visits per 100 persons per year), and whites have higher rates of visits than blacks (293.2 vs. 210.7 visits per 100 persons per year).³⁹ Participants were well educated. Forty-three percent had one or more of the chronic conditions we assessed, and 34 percent had one or more of the acute conditions. Preventive care was assessed for all participants; in addition, participants' care was assessed for 1.5 chronic or acute conditions, on average, for a total of 2.5 (range, 1 to 13). Participants were included in the overall denominator an average of 16 times (range, 2 to 304).

ANALYSIS OF CARE DELIVERED

Tables 3, 4, and 5 show the number of indicators included in the aggregate score, the number of persons eligible for one or more processes within the category, the number of times participants in the sample were eligible for indicators, and the weighted mean proportion (and 95 percent confidence interval) of recommended processes that were delivered.

Overall, participants received 54.9 percent of recommended care (95 percent confidence interval, 54.3 to 55.5) (Table 3). This level of performance was similar in the areas of preventive care, acute care, and care for chronic conditions. The level of performance according to the particular medical function ranged from 52.2 percent (95 percent confidence interval, 51.3 to 53.2) for screening to 58.5 percent (95 percent confidence interval, 56.6 to 60.4) for follow-up care.

"Mode" refers to the mechanism of care delivery required for the provision of the indicated process. Analysis of performance in terms of mode may identify areas in which system-wide interventions could offer solutions to problems of quality, such as improved methods for ordering, processing, and communicating laboratory results. We found greater variation among modes than among functions in adherence to the processes we studied (Table 4). Care requiring an encounter or other intervention (e.g., the annual visit recommended for patients with hypertension) had the highest rates of adherence (73.4 percent [95 percent confidence interval, 71.5 to 75.3]), and processes involving counseling or education (e.g., advising smokers with chronic obstructive pulmonary disease to quit smoking) had the lowest rates of adherence (18.3 percent [95 percent confidence interval, 16.7 to 20.0]). All pairwise differences were statistically significant at $P < 0.001$ except those between the prescribing of medication and care requiring an encounter or other intervention ($P = 0.02$), physical examination and immunization ($P = 0.001$), surgery and immunization ($P = 0.004$), and surgery and physical examination ($P = 0.05$). The difference between surgery and laboratory testing or radiography was not significant ($P = 0.39$).

PROBLEMS WITH QUALITY OF CARE

We also classified indicators according to the problem with quality that was deemed most likely to occur, and we found greater problems with underuse (46.3 percent of participants did not receive recom-

Table 2. Characteristics of the 6712 Participants.*

Characteristic	Value
Age (yr)	
Mean	45.5±0.2
Range	18-97
Female sex (%)	59.6±0.006
Nonwhite race (%)	18.6±0.005
Education (yr)	13.7±0.03
≥1 Chronic conditions (%)	44.7±0.006
≥1 Acute conditions (%)	36.3±0.006
No. of conditions and preventive care for which participants were eligible	
Mean	2.5±0.02
Range	1-13
No. of times participants eligible for indicators†	
Mean	15.8±0.17
Range	2-304

* Plus-minus values are means or percentages ±SE.

† The number of times a participant is eligible for an indicator is a function of the level at which the indicator is scored (participant, participant-provider dyad, or episode), the number of participants eligible for the specified process, and the number of indicators in the aggregate-score category.

mended care [95 percent confidence interval, 45.8 to 46.8]) than with overuse (11.3 percent of participants received care that was not recommended and was potentially harmful [95 percent confidence interval, 10.2 to 12.4]).

VARIATIONS IN QUALITY

Table 5 shows substantial variability in the quality-of-care scores for the 25 conditions for which at least 100 persons were eligible for analysis. Persons with senile cataracts received 78.7 percent of the recommended care (95 percent confidence interval, 73.3 to 84.2); persons with alcohol dependence received 10.5 percent of the recommended care (95 percent confidence interval, 6.8 to 14.6). The aggregate scores for individual conditions were generally not sensitive to the presence or absence of any single indicator of quality.

DISCUSSION

Overall, participants received about half of the recommended processes involved in care. These defi-

Table 3. Adherence to Quality Indicators, Overall and According to Type of Care and Function.

Variable	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)*
Overall care	439	6712	98,649	54.9 (54.3–55.5)
Type of care				
Preventive	38	6711	55,268	54.9 (54.2–55.6)
Acute	153	2318	19,815	53.5 (52.0–55.0)
Chronic	248	3387	23,566	56.1 (55.0–57.3)
Function				
Screening	41	6711	39,486	52.2 (51.3–53.2)
Diagnosis	178	6217	29,679	55.7 (54.5–56.8)
Treatment	173	6707	23,019	57.5 (56.5–58.4)
Follow-up	47	2413	6,465	58.5 (56.6–60.4)

* CI denotes confidence interval.

Table 4. Adherence to Quality Indicators, According to Mode.

Mode	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)*
Encounter or other intervention	30	2843	4,329	73.4 (71.5–75.3)
Medication	95	2964	8,389	68.6 (67.0–70.3)
Immunization	8	6700	9,748	65.7 (64.3–67.0)
Physical examination	67	6217	19,428	62.9 (61.8–64.0)
Laboratory testing or radiography	131	5352	18,605	61.7 (60.4–63.0)
Surgery	21	244	312	56.9 (51.3–62.5)
History	64	6711	36,032	43.4 (42.4–44.3)
Counseling or education	23	2838	3,806	18.3 (16.7–20.0)

* CI denotes confidence interval. All pairwise differences were statistically significant at $P < 0.001$ except those between medication and encounter or other intervention ($P = 0.02$), physical examination and immunization ($P = 0.001$), surgery and immunization ($P = 0.004$), and surgery and physical examination ($P = 0.05$). The difference between surgery and laboratory testing or radiography was not significant ($P = 0.39$).

cits in care have important implications for the health of the American public. For example, only 24 percent of participants in our study who had diabetes received three or more glycosylated hemoglobin tests over a two-year period. This finding parallels the finding by Saaddine and colleagues that 29 percent of adults with diabetes who participated in the nationally representative Behavioral Risk Factor Surveillance System reported having their blood sugar tested during the previous year.¹⁸ This routine monitoring is essential to the assessment of the effectiveness of treatment, to ensuring appropriate responses to poor glycemic control, and to the identification of complications of the disease at an early stage so that serious consequences may be prevented. In the United Kingdom Prospective Diabetes Study, tight blood glucose control and biannual monitoring decreased the risk of microvascular complications by 25 percent.⁴⁰

In our study, persons with hypertension received 64.7 percent of the recommended care (95 percent confidence interval, 62.6 to 66.7). We have previously demonstrated a link between blood-pressure control and adherence to process-related measures of quality of care for hypertension.⁴¹ Persons whose blood pressure is persistently above normal are at increased risk for heart disease, stroke, and death.⁴² Poor blood-pressure control contributes to more than 68,000 preventable deaths annually.⁴³

Overall, 68.0 percent (95 percent confidence interval, 64.2 to 71.8) of the recommended care for coronary artery disease was received, but only 45 percent of persons presenting with a myocardial infarction received beta-blockers, which reduce the risk of death by 13 percent during the first week of treatment and by 23 percent over the long term.⁴⁴ Only 61 percent of participants with a myocardial infarction who were appropriate candidates for aspirin therapy received aspirin, which has been shown in randomized trials to reduce the risk of death from vascular causes by 15 percent, to reduce the risk of nonfatal myocardial infarction by 30 percent, and to reduce the risk of nonfatal stroke by 40 percent.⁴⁵

Deficits in processes involved in primary and secondary preventive care are also associated with preventable deaths. Among elderly participants, only 64 percent had received or been offered a pneumococcal vaccine; nearly 10,000 deaths from pneumonia could be prevented annually by appropriate

vaccinations.⁴³ About 38 percent of participants had been screened for colorectal cancer; annual fecal occult-blood tests could prevent about 9600 deaths annually.⁴³

Nonresponse bias is a potential limitation of the study. Because the sample we analyzed included 37 percent of the eligible adults, the results are likely to be biased, but the direction of that bias is not clear. For example, because our participants were more likely to use the health care system than were eligible persons who did not participate in the study, our results may be biased toward an underestimation of deficits in quality related to underuse.

The study relied primarily on the review of medical records to score indicators, which may lead some to conclude that we have identified problems with documentation rather than quality. This issue has been examined in studies that compared process-based quality scores using standardized patients, vignettes, and abstraction of medical records⁴⁶ and studies that compared standardized patients with audiotapes of encounters.⁴⁷ Overall, the process scores among the four conditions studied were 5 percentage points lower with the use of medical records than with the use of vignettes and 10 percentage points lower with the use of medical records than with the use of standardized patients. About two thirds of the disagreement between data from standardized patients and data from audiotapes was attributable to reports by standardized patients that they received care processes that were not confirmed by audiotape. A related study reported a false positive rate of 6.4 percent in medical-record documentation, with the highest false positive rates found for physical examination and elements of the diagnostic process.⁴⁸ Thus, our scores might have been as much as 10 percentage points higher if we had used a different method of obtaining data. We used the interview about the participant's health history to partially offset this effect. For example, among elderly participants, only 15 percent had a note in any chart indicating that an influenza vaccination had been received, but 85 percent reported having received one. In general, the inclusion of self-reported data improved scores.

Our results indicate that, on average, Americans receive about half of recommended medical care processes. Although this point estimate of the size of the quality problem may continue to be debated, the gap between what we know works and what is

Table 5. Adherence to Quality Indicators, According to Condition.*

Condition	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)
Senile cataract	10	159	602	78.7 (73.3–84.2)
Breast cancer	9	192	202	75.7 (69.9–81.4)
Prenatal care	39	134	2920	73.0 (69.5–76.6)
Low back pain	6	489	3391	68.5 (66.4–70.5)
Coronary artery disease	37	410	2083	68.0 (64.2–71.8)
Hypertension	27	1973	6643	64.7 (62.6–66.7)
Congestive heart failure	36	104	1438	63.9 (55.4–72.4)
Cerebrovascular disease	10	101	210	59.1 (49.7–68.4)
Chronic obstructive pulmonary disease	20	169	1340	58.0 (51.7–64.4)
Depression	14	770	3011	57.7 (55.2–60.2)
Orthopedic conditions	10	302	590	57.2 (50.8–63.7)
Osteoarthritis	3	598	648	57.3 (53.9–60.7)
Colorectal cancer	12	231	329	53.9 (47.5–60.4)
Asthma	25	260	2332	53.5 (50.0–57.0)
Benign prostatic hyperplasia	5	138	147	53.0 (43.6–62.5)
Hyperlipidemia	7	519	643	48.6 (44.1–53.2)
Diabetes mellitus	13	488	2952	45.4 (42.7–48.3)
Headache	21	712	8125	45.2 (43.1–47.2)
Urinary tract infection	13	459	1216	40.7 (37.3–44.1)
Community-acquired pneumonia	5	144	291	39.0 (32.1–45.8)
Sexually transmitted diseases or vaginitis	26	410	2146	36.7 (33.8–39.6)
Dyspepsia and peptic ulcer disease	8	278	287	32.7 (26.4–39.1)
Atrial fibrillation	10	100	407	24.7 (18.4–30.9)
Hip fracture	9	110	167	22.8 (6.2–39.5)
Alcohol dependence	5	280	1036	10.5 (6.8–14.6)

* Condition-specific scores are not reported for management of pain due to cancer and its palliation, management of symptoms of menopause, hysterectomy, prostate cancer, and cesarean section, because fewer than 100 people were eligible for analysis of these categories. CI denotes confidence interval.

actually done is substantial enough to warrant attention. These deficits, which pose serious threats to the health and well-being of the U.S. public, persist despite initiatives by both the federal government and private health care delivery systems to improve care.

What can we do to break through this impasse? Given the complexity and diversity of the health care system, there will be no simple solution. A key component of any solution, however, is the routine availability of information on performance at all levels. Making such information available will require a major overhaul of our current health information systems, with a focus on automating the entry and retrieval of key data for clinical decision making and for the measurement and reporting of quality.⁴⁹

Establishing a national base line for performance makes it possible to assess the effect of policy changes and to evaluate large-scale national, regional, state, or local efforts to improve quality.

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Improving the Quality of Care — Can We Practice What We Preach?

Earl P. Steinberg, M.D., M.P.P.

It has been 30 years since Wennberg and Gittelsohn published their landmark article demonstrating substantial variation among different geographic areas in the provision of medical services.¹ Since then, investigators have found variation in the delivery of virtually every aspect of health care that has been examined. From the perspective of the quality of care, the variation that is the greatest cause for concern is that between actual practice and evidence-based "best practice."

Over the past 30 years, progress has been made in several areas that are vital to quality improvement. Practice guidelines have become more rigorously evidence-based and are now packaged in ways that make it easier to put them into practice. Tremendous progress has been made in the development of valid, reliable, and practical measures of the quality of care² that are now applied in managed care³ and fee-for-service settings.⁴ There are many indications of an increased focus on quality, and we have made great progress in our understanding of factors that contribute to substandard quality² and of interventions that do (and those that do not) improve the quality of care.^{2,5,6}

In this issue of the *Journal*, McGlynn and colleagues⁷ report the results of a large national study of the content of care provided to adults between 1996 and 1998. Although the "headline" finding of the study is that adults received 55 percent of recommended care according to 439 process-of-care measures, the most enlightening findings are those in the measure-specific results. The biggest limitation of the study derives from the likelihood that documentation was poor in the charts that were

used to determine what care patients had received. Because of this limitation, along with the focus on compliance with multiple recommendations for the management of a given clinical condition rather than on how well the condition was controlled, it would not be appropriate to interpret the findings of this study as showing that a typical adult in the United States has a 50–50 chance of receiving adequate care of a particular clinical condition. Nonetheless, the study adds detailed information to a substantial body of research that shows that the quality of the care delivered in the United States is considerably lower than it should be.⁸

What will it take to do better? Four actions are likely to have the greatest effect. First, quality of care should be measured and reported routinely at both the national and provider-specific (e.g., hospital and physician) levels. In September 2003, the Agency for Healthcare Research and Quality will publish the first annual National Healthcare Quality Report, which will include 150 measures. A separate effort is needed, however, to report on the quality of care delivered by individual facilities and physicians. Such an effort would benefit from the involvement of professional societies in measurement and quality-improvement activities.⁹ Both types of activities are consistent with the missions of professional societies. Examples of such leadership, as well as the benefits of it, can be observed in the Dialysis Outcomes Quality Initiative of the National Kidney Foundation,¹⁰ the End-Stage Renal Disease (ESRD) Clinical Performance Measures Project,¹¹ and the Guidelines Applied in Practice Initiative of the American College of Cardiology.¹²

Problems with the quality of data and statistical challenges will need to be overcome in order to assess quality at the level of the provider,¹³ but these problems and challenges are surmountable. Incentives can be put into place for physicians and hospitals to improve the completeness and accuracy of their data. The number of observations available for analysis of a single physician or group of physicians can be increased through the aggregation of data from different health plans and insurers and through the combining of data for different measures of clinical performance.

Second, we must make greater use of information technology. Given the rate at which diagnostic and therapeutic advances are being made, the number of data elements pertinent to the provision of high-quality care, the dispersion of those data elements throughout a highly fragmented delivery system, and the increased number of patients to whom many physicians now provide care, it is ludicrous to expect physicians to comply consistently with hundreds of practice guidelines without the support of a computerized infrastructure. Decision-support tools, including reminders, improve the quality of care.^{6,14} I reliably receive reminders when my dog needs a vaccination and when my car is due for maintenance. Physicians and patients should also receive computer-driven reminders.

For financial and practical reasons, during the next decade, we should increase the use of comparatively inexpensive decision-support tools that are applied to data already being collected in computerized form, rather than expect the widespread installation of computerized patient records or incremental data collection. Because decision support is likely to be most effective at the time when decisions are being made, payers should experiment with inexpensive electronic techniques for transmitting relevant information to physicians on the day a patient is to be seen, and hospitals should install computerized ordering systems that are integrated with decision-support tools. Over the longer term, a significant investment needs to be made in an infrastructure for quality improvement. Since Medicare is the payer that will benefit the most financially from quality-improvement efforts focused on chronic disease, it is in the long-term interest of the federal government to invest in the development of information technology and a care-support infrastructure that will facilitate quality improvement.

Third, in addition to capitalizing on the power of computers, we should draw on the power of pa-

tients to improve the quality of care they receive and their health outcomes. We cannot achieve meaningful "consumer-driven health care," however, simply by increasing consumers' financial stake in the cost of that care. To engage consumers and empower them to take increased responsibility for their health and health care, we need to provide them with information about the care they should receive and consider receiving. To be effective, that information needs to be authoritative, easily accessible, easy to understand and to act on, timely, and personalized.

The fourth and biggest problem that must be addressed is the fact that current financial incentives often discourage quality improvement.¹⁵ Improved compliance with some of the quality measures used in the study by McGlynn et al.⁷ will require investments and increased health care expenditures in the short term, without any compensating cost savings over the long term. Improved compliance with other measures will yield savings that exceed the cost of achieving them, but those savings may not be realized for 5 to 10 years. In a market in which people often change health plans every year or two, health plans lack an economic incentive to invest in quality-improvement initiatives that will require 5 to 10 years to achieve an economic return on investment.¹⁵ Physicians and hospitals often face an outright economic disincentive to invest in infrastructure that will improve compliance with best practices.¹⁵ The challenge, therefore, is not to demonstrate that there already is a "business case" for quality improvement in health care; rather, it is to establish new incentives that will create such a case. Potential strategies for creating this case include tying incremental payment to improved clinical performance or investment in information technology designed to promote quality improvement; providing economic incentives for patients to use providers with profiles of high-quality care; providing grants to health plans and hospitals, and creating tax incentives for physicians, to invest in information technology that will support quality improvement; and reducing malpractice insurance premiums or lowering ceilings on potential claims for providers that use certain types of quality-improvement infrastructures, or both.

Underuse and overuse of care, and errors that occur in the course of providing services that are appropriate, are a predictable result of our current system of care. Thus, although many of the findings reported by McGlynn et al.⁷ may cause concern, they are not surprising. We can and should take concert-

ed action to ensure that future studies document substantial improvement.

Dr. Steinberg reports having equity interests in Resolution Health.

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A cure for cardiovascular disease?

Combination treatment has enormous potential, especially in developing countries

See *Papers* pp 1419, 1423, and 1427

Today's *BMJ* contains one of the boldest claims for a new intervention—"a greater impact on the prevention of disease in the Western world than any other known intervention." Is it a new magic bullet for cancer or a new gene therapy? No, it is a new strategy to deliver some of our most well known medicines. Wald and Law propose that a single pill containing aspirin, a statin, three blood pressure lowering agents in half dose, and folic acid is provided to people with vascular disease and those aged over 55 years. They synthesise an enormous amount of information (including over 750 trials with 400 000 participants) to estimate that the pill would reduce heart disease and risk of stroke by over 80%, while causing symptoms warranting withdrawal of the pill in one to two per 100 and fatal side effects in less than one in 10 000 users. If this were correct the benefits would substantially outweigh hazards in people with vascular disease (who have more than a one in five chance of a major event over five years without treatment) and many others at higher risk.

Will the benefits be so great? All the components except folic acid have unequivocal evidence of benefits across the board, shown by randomised trials in different groups of patients. Large trials with folic acid are ongoing, and existing evidence is very encouraging. Lowering cholesterol concentrations that are above 4.0 mmol/l and blood pressure values above 120/80 mm Hg is likely to confer benefit even though many early trials and much clinical practice focuses on people with hypercholesterolaemia or hypertension. Wald and Law argue convincingly that three blood pressure lowering agents at half the standard dose are the best way to achieve large reductions in blood pressure, which are the main, if not only, mechanism of benefit of these agents.¹ Since average levels of risk factors tend to be so far from optimal ones in developed countries, large reductions in risk factors are likely. However, at least among those without vascular disease the average effects may be less than the proposed 20/10 mm Hg and 1.8 mmol/l low density lipoprotein, leading to less marked risk reductions. None the less, one could reasonably expect more than a halving in cardiovascular risk in the first two years and a two thirds reduction in subsequent years. These joint effects are best estimated as the product of separate relative risks, since clinical trials show similar sized benefits from, for example, statins with and without aspirin. Wald and Law's combined estimates are consistent with previous ones.¹

Will the side effects be so low? Contrary to many perceptions, these drugs have remarkably few side

What is needed to realise the potential benefits?

Widespread debate on the new paradigm

Technical solutions in developing and manufacturing the pill(s) so that chemical activity is maintained

Explicit regulatory requirements, ideally based on balance of benefit and harm rather than principles that fixed dose polypharmacy is intrinsically undesirable

Trials assessing bioavailability, intermediate endpoint effects, safety, tolerability, and adherence (clinical endpoint trials should not be needed for existing indications)

Ensuring those in need get access—clear indications and contraindications, affordable formulations and systems to ensure profits are made on large volumes rather than large margins

effects. Placebo controlled trials show that when people stop treatment it is rarely for pharmacological reasons. More information from trials on side effects from low dose combinations is clearly needed, especially before contemplating widespread use among people at moderate risk. However, common or serious unanticipated problems seem unlikely since these medications have been studied so extensively and used together so often.

To whom should this new intervention be offered? The history of symptomatic vascular disease is least controversial, and the need is great—most such people are undertreated, even in developed countries,² despite being at highest risk. More controversial will be treating every person over the age of 55 although this debate should not detract from the size and certainty of net benefits in those with vascular disease. Age is of course the best proxy for exposure to life, and life in developed countries at present almost inescapably entails long term exposure to major risks, such as excess intake of salt and saturated fat. There are simple ways for more focused targeting of people at high absolute risk³ that would entail treating far fewer people.

What is needed to realise the benefits of this approach? Key steps are outlined in the box, and some are expanded below.

Further debate is required among health professionals and regulatory authorities. Routine use of a "polypill" among, for example, survivors of ischaemic stroke would minimise undertreatment while at the same time reducing opportunities for tailoring

(although that is still possible with different versions of the pill). Treating when benefit outweighs harm is accepted, but treating risk rather than risk factor thresholds is new. This strategy was proposed a decade ago,⁷ and guidelines have developed that cross disciplines,⁸ but traditional paradigms such as treatment of hypertension still predominate.

A wider debate is needed across society about extensive use of preventive medications, especially among people without symptomatic disease. Widespread uptake would require overcoming perceptions that cardiovascular disease is a "natural" cause of death, or one that does not lead to substantial disability. One must also bear in mind that a third or more of adults in many countries already take natural supplement pills regularly (mostly multivitamins with uncertain benefits, or antioxidants, now known to have no important benefits for major diseases). The strategy should be integrated with population wide approaches that address the root causes of cardiovascular disease, including reshaping societies so that smoking and development of life threatening levels of body fat, cholesterol, and blood pressure are not the norm.

Finally, the most important challenge is ensuring such interventions reach the many people at high risk in developing countries who currently receive little or no preventive care. Compared with developed countries many times more lives could be saved, mostly among middle aged people, if combination medications were made affordable and accessible. It would clearly have major equity implications if the decades of research in developed countries showing how to control cardiovascular disease were not translated into practicable solutions for developing countries, which are now facing an epidemic of cardiovascular disease.⁹ Cost will be the key. The strategy requires many fewer measurements, and the pill need not be expensive—off patent components could cost very little.⁵ It is more cost effective than threshold based strategies (for example, the treatment of hypertension)^{5 10} and,

combined with population wide initiatives such as reduced salt in manufactured foods, could halve population levels of cardiovascular disease.⁵

So is Wald and Law's bold claim justified? Quite possibly. Only large reductions in smoking or a few other leading health risks could achieve so much health gain.¹¹ Realising this enormous potential should be a major goal especially for developing countries.

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Managing chronic pain in children and adolescents

We need to address the embarrassing lack of data for this common problem

Recent epidemiological data have made nonsense of the prejudice that chronic pain is a uniquely adult problem. Chronic and recurrent pain in children and adolescents is now known to have a point prevalence of at least 15%.¹ Girls report more pain than boys, and the incidence peaks at an average age of 14 years. The most common complaint is headache, followed by recurrent abdominal pain and musculoskeletal pain.²

Many of the children and adolescents with chronic and recurrent pain will be managed effectively by the family doctor or may simply never come to professional attention. However, a noteworthy number of children and their families are severely affected by pain. Doctors concerned about missing a serious

underlying disease invest time and energy in investigating the child and referring to specialists for further evaluation. During the time spent in this "diagnostic vacuum," the child often receives little appropriate pain management. If, as is usually the case, no specific cause can be found the child, family, and doctor often become frustrated, sometimes antagonistic towards each other, and the management of the pain goes wanting. It is this time spent in the search for meaning and cure that is thought to be crucial to how the patient and family adjust to pain. Fear and frustration are often fuelled by unhelpful or inaccurate diagnoses such as "functional" or "psychosomatic" pain. Families often interpret these labels as blaming them for the child's pain, and the labels tend to reinforce

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